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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/630,883

07/30/2003

Seth A. Foerster

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT

PAPER NUMBER

3736

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/630,883	Applicant(s) FOERSTER ET AL.	
	Examiner Brian Szmal	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2009 and 30 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Oath/Declaration

1. This application presents a claim for subject matter not originally claimed or embraced in the statement of the invention. Claims 53, 54 and 58 contain subject matter similar to the preliminary amendment filed on July 30, 2003. The claims contain subject matter that is not fully disclosed in the current specification. In particular, the current specification is silent with respect to the creation of a cavity site from which a tissue sample has been removed during a breast biopsy. A supplemental oath or declaration is required under 37 CFR 1.67. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Priority

2. The Applicants claim priority to 08/308,097, filed on September 16, 1994. However, due to the fact that the above-mentioned claimed subject matter is not directly disclosed in the current specification, the current application is being treated as a Continuation-In-Part, with the effective filing date of July 30, 2003.

Claim Objections

3. Claim 53 is objected to because of the following informalities: In line 3, "r emote" should read as "remote". Appropriate correction is required.

Claim Rejections - 35 USC § 112

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4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation: “when the marker is disposed in a biopsy cavity created when the tissue has been removed” is not taught or suggested in the current specification.

6. Claims 54-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 54 discloses a method step of “removing tissue to form a biopsy cavity”. The current specification fails to support this limitation. The current specification only discloses the use of a biopsy device to place the biopsy marker at a location, not creating a cavity in tissue via the removal of a tissue sample.

7. Claims 54-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 56 and 57 disclose the use of a radiopaque material. Claim 54 discloses the use of ultrasound to detect the marker once placed within the tissue. Claims 56 and 57, in conjunction with the disclosure of Claim 54, disclose an embodiment of the marker wherein the marker is imaged via two different imaging systems since ultrasound imaging does not use radiopaque substances to detect markers placed within tissue. Likewise Claims 61 and 62, in conjunction with Claim 58, disclose an embodiment of the marker wherein the marker is imaged via two different imaging systems since ultrasound imaging does not use radiopaque substances to detect markers placed within tissue. Radiopaque materials are only used to view the implanted marker via x-ray, mammography, and CAT scans. Radiopaque materials are not viewable using ultrasound. Furthermore, the current specification fails to disclose the ultrasonic detection of a marker using radiopaque material.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 53-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al (6,161,034) in view of Wolff et al (5,545,208).

Burbank et al disclose a means for marking a biopsy site and further disclose placing a mass or article of biodegradable material into the cavity site created by a biopsy, and imaging the implanted mass by using ultrasound. See Column 4, lines 59-62; Column 5, lines 47-64; Column 7, lines 47-67.

Burbank et al however fails to disclose a compressed woven mass of imageable biodegradable material.

Wolff et al discloses a biodegradable, self-expandable stent and further disclose the use of a contrast media for remote imaging. See Column 6, lines 62-63; Column 7, lines 25-28 and 45-49.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the marker element of Burbank et al to use an expandable biodegradable imageable woven article, as per the teachings of Wolff et al, since it would provide a means of marking a biopsy site that can be remotely imaged as well as being palpable to relocate the biopsy site.

Response to Arguments

10. Applicant's arguments filed January 24, 2011 have been fully considered but they are not persuasive.

The Applicant argues the above requirement for a new oath/declaration is improper due to the fact that the claim language is clearly set forth in the parent application 08/308,097. The Applicant also argues one of ordinary skill in the art "would inherently understand that 'the creation of a cavity site from which a tissue sample has

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been removed during a biopsy' is inherent in the disclosure". The Applicant attempts to provide specific locations in the current specification for the support for the removal of a tissue sample to create a cavity site. The Applicant also argues the 112 rejections pertaining to the lack of disclosure of a "biopsy cavity" in the current specification are also improper due to the previously discussed locations in the current specification that provide inherent disclosure of the claimed subject matter. The Examiner disagrees with the Applicant's assertions. In Appeal No. 2009-002192 and the associated Appeal Brief, filed in US Pat Application No. 10/943,433 (available via Public PAIR and/or the USPTO BPAI website), the current assignee and law firm placed clearly on the record that Foerster et al (08/308,097, issued as 6,288,055) does not teach or suggest the creation of a cavity site using a biopsy device in order to place a biopsy marker in a cavity created after the removal of the biopsy sample. Instead, it is disclosed on Page 6 of the BPAI decision that the Appellant argued Foerster et al: **"Rather, Foerster explicitly discloses ... marker elements are not intended to be placed at a biopsy site at the time of taking a tissue sample, but are intended to mark the border of a lesion for later diagnostic or therapeutic procedures."** (App. Br. 9-10.) **Appellants argue that "Foerster intends to mark the site of a lesion so that a lesion may be treated at a later time."** (App. Br. 10.); **"Appellants argue that, "[g]iven that Foerster is marking a lesion location prior to its treatment, Foerster would certainly not wish to place anything adjacent the lesion site that would distort or otherwise change the natural shape of the lesion site."** (App. Br. 10.); and also disclose on page 8: **"the Appellants believe Foerster does not take a biopsy sample prior to marking**

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the site". The assignee's written arguments to the BPAI clearly place on the record that the current specification fails to support any creation of a biopsy cavity, but instead only discloses the placement of a marker adjacent to a suspected lesion for alter treatment. Therefore, there is no inherent disclosure of a creation of a biopsy cavity. Due to the similarity of the claim language between the July 30, 2003 preliminary amendment and the current claims, and the lack of a clear disclosure in the specification of the creation of a cavity within tissue after the removal of a biopsy sample, a new oath/declaration is properly required, and the treatment of the current earliest priority date to July 30, 2003 is also proper.

The Applicant also argues the 112 rejection pertaining to the use of radiopaque materials and the ability to use ultrasound to detect the implanted marker element. The Applicant argues the disclosure of "substantially radiopaque material" in the specification at page 9, lines 14-19, "does not foreclose other materials such as ultrasonically detectable materials could be contained in the marker element". The Examiner respectfully disagrees. The disclosure of "substantially radiopaque materials" does not allow for any other type of remotely detectable materials, including ultrasonically detectable materials. Radiopaque materials can only be detected through the use of x-rays. Per MedTerms.com medical dictionary, radiopaque is defined as: *"Anything that does not let X-rays or other types of radiation penetrate. Radiopaque objects block radiation. They are opaque to radiation. A metal object, for example, is typically radiopaque. If a child swallows a coin and it goes down into the stomach, it is easily visible in the stomach on an X-ray because it is radiopaque."* Ultrasound is not a

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type of radiation, because ultrasound is not part of the electromagnetic spectrum. Based on the accepted, well-known definition of radiopaque, one of ordinary skill in the art would not interpret the disclosed “substantially radiopaque materials” as including other materials such as ultrasonically detectable materials. Therefore the current specification fails to disclose the use of ultrasonically detectable materials.

The Applicants then argue Burbank et al does not constitute prior art, based on the Applicant’s previous arguments, and therefore the rejection is improper and should be withdrawn. As presented above, the current specification does not teach or suggest, inherently or expressly, the removal of tissue to form a cavity or a biopsy location. Since the claim language was first disclosed in a preliminary amendment filed on July 30, 2003, the claim language can be incorporated into the current specification. However, such an incorporation would cause the current application to be treated as a CIP, with an earliest priority date of July 30, 2003, and not September 16, 1994. Due to the current status as a CIP, with a priority date of July 30, 2003, Burbank et al does in fact qualify as prior art, and therefore the rejection is being maintained.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Brian Szmal/

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736